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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,951	06/23/2003	Shu Wang Zheng	USP2124A-FPI	7868
30265	7590	12/13/2005	EXAMINER	
RAYMOND Y. CHAN 108 N. YNEZ AVE., SUITE 128 MONTEREY PARK, CA 91754			GOUGH, TIFFANY MAUREEN	
			ART UNIT	PAPER NUMBER

1651

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/601,951

Applicant(s)

ZHENG ET AL.

Examiner

Tiffany M. Gough

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____  | 6) <input type="checkbox"/> Other: ____                                     |

***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in China on 06/25/2002. It is noted, however, that applicant has not filed a certified copy of the 02135141.4 application as required by 35 U.S.C. 119(b).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "predetermined" in claims 1-20 renders the claims indefinite. The term "predetermined" is not defined by the claims. The recitation of the word "predetermined" can be interpreted in many ways and is therefore unclear what is applicant's intention. It is unclear in claim 1 and therefore all dependent claims whether the "predetermined concentration" refers to the aqueous solution or the stevioside. The "predetermined stevioside" is interpreted as a specific stevioside not mentioned in the specification. Stevioside is a component associated with the sweetness properties of *Stevia Rebaudiana* Bertoni and is not known as stevioside A,B,C,D or E like the rebaudioside component associated with sweetness of *Stevia Rebaudiana* Bertoni, therefore the intended scope of the claim is unclear.

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It is unclear in claim 1(b) where applicant claims "...substrate is capable of being added to define as predetermined reactants..." The phrase "...capable of being added to define as..." is worded awkwardly and is unclear.

In essence of the invention and achieving a specific percentage yield, it is unclear how to predetermine reaction times, temperatures, values and such in order to achieve a specific percentage yield.

Applicant claims a substrate, an alpha-glucosyl sugar compound, selected from the group of starch, dextrin, and cyclodextrin and a transferase selected from the group of glucosyltransferase and cyclodextrin glucanotransferase. Applicant claims the process of allowing these substrates and transferases to react to form a reacting solution. Applicant does not specify which substrate is reacting with which transferase in order to form the proper reacting solution. Not all starch, dextrin and cyclodextrins have the same DE values and concentrations nor do they all favour the action of a glucosyltransferase and a cyclodextrin glucanotransferase, i.e., the substrate/enzyme specificity. For example, a cyclodextrin or alpha-glucosyl sugar compounds ranging from gelatinized starch product with DE not higher than 1 to a partial starch hydrolyzate with DE of about 60 is a suitable substrate for the action of cyclodextrin glucanotransferase, therefore indicating not all starch, dextrin, and cyclodextrins are suitable for reaction with the specific enzyme. It is suggested that applicant clearly define the substrate/enzyme relationship.

Claims 5, 8, 11, 14, 17, 18, and 20 recites the limitation "said transferase ratio". There is insufficient antecedent basis for this limitation in the claim.

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Applicant does not claim a transferase ratio in claim 1. All dependent claims are also rejected.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant claims a process of improving the quality of taste of a natural sweetener for mass production comprising the steps of; providing a predetermined stevioside in an aqueous solution having a predetermined

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concentration (10-18%, ultimately 14%); adding a predetermined substrate, an alpha-glucosyl sugar compound, such as starch, dextrin and cyclodextrin, with a predetermined DE value (4-30, ultimately 16) and concentration (10-19%, ultimately 15%) to the stevioside; mixing stevioside and the substrate to form a starting solution; adding a predetermined transferase selected from the group of glucosyltransferase and cyclodextrin glucanotransferase, with a predetermined quantity to the starting solution to form a reacting solution; allowing the reacting solution to react for a reaction time (3-30 hours, ultimately 18), under a controlled temperature (40-80°C, ultimately 66°C) to form a product of  $\alpha$ -glycosyl stevioside giving a percentage yield b/w 75-86, ultimately 86%.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyake (U.S. Patent 4,219,571 Aug. 26, 1980). Miyake teaches a process for producing a sweetener, characterized by the subjection of an aqueous solution containing stevioside (concentration between 0.1-20%) and one or more alpha-glucosyl sugar compounds such as, starch, maltooligosaccharides, or compounds containing alpha-glucosyl residues such as sucrose (concentration range of 1-50% and DE values between 10-70), to an alpha-glucosyltransferase, cyclodextrin glucanotransferase, or any alpha-glucanotransferase as long as it forms alpha-glycosyl stevioside without decomposing stevioside when allowed to react. The stevioside aqueous solution and alpha-glycosyl sugar compound is heated to dissolve stevioside and gives a stevioside concentration of about 0.1-20% with an alpha-glycosyl sugar concentration of about 1-50%. The temperature of the reaction is within the range of 20-80° C, the reaction time is in

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about 5-80 hours, and the percentage yield ranges from about 60-97%. See column 5, paragraph 2, column 6, paragraphs 2 and 3.

Miyake does not teach a resulting product yield between 75-86%.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention to use stevioside in an aqueous solution having a concentration of 14%, adding an alpha-glucosyl sugar substrate such as starch, dextrin and/or cyclodextrin having a DE value of 16 and concentration of 15%, mixing the two to form a starting solution, subjecting the starting solution to the action of a transferase such as glucosyltransferase and/or cyclodextrin glucanotransferase to obtain an alpha-glucosyl stevioside product with a yield between 75-86% because Miyake clearly teaches a range of concentrations and conditions to be successful in producing alpha-glycosyl stevioside with a yield of 60, 90 and 95%. The reaction conditions applicant claims such as reactant concentrations, the reaction time of 18 hours, temperature to be carried out at 66°C and a final product percentage yield of 86% are result effective variables and therefore obvious because applicants invention lies within the ranges Miyake et al teach. Moreover, the prior art teaches the ranges and the limitations of the claims. One of ordinary skill in the art, given what is known in the art at the time the invention was made, would have a reasonable expectation of success to perform the reaction with conditions which fall within the ranges known to be effective in achieving the final product. Therefore, it would have been obvious to perform the reaction containing the claimed reaction components, conditions and the claimed percentages as a matter of optimization of these result effective variables. One

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would expect reasonable success in obtaining a final product yield of 86%  $\alpha$ -glycosyl stevioside, under the claimed reaction conditions, given the reaction conditions Miyake teach to obtain a final product yield of 60, 90 and 95%.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."). See MPEP 2144.05

Thus the claimed invention as a whole is prima facie obvious over the prior art.

### ***Conclusion***

No claims are allowed.




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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany M. Gough whose telephone number is 571-272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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LEON B. LANKFORD, JR.  
PRIMARY EXAMINER